K003752

MAR 2 3 2001

510(k) Summary

1) Submitter's Name Address, contact

BIOSAFE Diagnostic Corporation
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Contact Person: Jack A. Maggiore, PhD
BIOSAFE Laboratories, Inc.
(773) 693-0400, x253

Date Prepared: November 30, 2000

2) Device Name

Proprietary Name: BIOSAFE Capillary Blood Transport System for Testing Thyroid Stimulating Hormone (TSH)

Common Name: Capillary blood collection and transportation System for TSH

Classification Name: Thyroid Stimulating Hormone (21 CFR 862. 1690)

3) Predicate Device

London Diagnostics, Inc. Lumitag ™ TSH Chemiluminescence Immunoassay (K881443). Nichols Institute Diagnostics acquired London Diagnostics, Inc. in 1992. The kit is now marketed as *The Nichols Institute Diagnostics TSH-Third Generation Kit*. All kit components have remained essentially the same as the London Diagnostics Kit in 1988.

4) Device Description

The device is a kit containing the materials necessary to collect a whole blood capillary sample into a blood transport device for storage and transport to a certified clinical laboratory for testing thyroid stimulating hormone (TSH). The kit is comprised of a blood transport device in a resealable foil pouch, alcohol prep pad, disposable lancets, gauze pad, bandage strip, collection instructions, insulated shipping box, leakproof bag, return prepaid envelope, and a patient test authorization form.

5) Intended Use

The BIOSAFE Capillary Blood Transport System for Testing Thyroid Stimulating Hormone (TSH) is intended for prescription distribution, and is a clinic-use device for collection and transportation of capillary blood for *in vitro* diagnostic quantitative determination of TSH. The device will be used for measuring whole blood TSH levels in human adults. This device is not intended for the diagnosis of thyroid disease in neonates.

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510(k) Summary, continued

6) Comparison to predicate device	The *BIOSAFE Capillary Blood Transport System (BTS) for Testing TSH* has technological characteristics and an intended use that are substantially equivalent to that of the predicate device, Nichols Institute Diagnostics Chemiluminescence 3rd Generation TSH Assay. The BIOSAFE BTS provides additional components that permit collection, storage, and transportation of a capillary whole blood sample to a certified clinical laboratory for analysis. Both kits are intended for testing clinic collected blood for *in vitro* diagnostic laboratory determination of TSH. The laboratory analysis for the BIOSAFE System, uses Nichols Institute Diagnostics 3rd Generation TSH Chemiluminescence Immunoassay for the determination of TSH. Determination of capillary whole blood TSH using the BIOSAFE BTS is substantially equivalent to serum TSH values using the Nichols Institute Diagnostics 3rd Generation Chemiluminescence Immunoassay.
7) Performance Studies	Determination of capillary whole blood TSH using the BIOSAFE BTS is substantially equivalent to serum TSH values using the Nichols Institute Diagnostics 3rd Generation Chemiluminescence Immunoassay. Performance studies were conducted on blood samples collected by trained health care professionals at four different geographical sites in three different time zones. A corresponding venous blood sample was collected by the health care professional in order to compare whole blood sample results to those obtained from capillary blood samples collected on the BIOSAFE BTS for TSH. All samples collected were mailed directly back to BIOSAFE Laboratories for determination of TSH by Nichols Institute Diagnostics 3rd Generation Chemiluminescence Immunoassay.
8) Test Summary	Performance characteristics studied included precision and correlation. In addition, the BIOSAFE BTS for TSH determination was evaluated for reagent and sample stability when exposed to abusive conditions.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

MAR 2 3 2001

Jack A. Maggiore, Ph.D.
Director, Clinical Trials
BIOSAFE Diagnostics Corporation
100 Field Road – Suite 240
Lake Forest, IL 60045

Re: K003752
Trade Name: BIOSAFE Capillary Blood Transport System for Testing Thyroid Stimulating Hormone (TSH)
Regulatory Class: II
Product Code: JLW, JKA
Dated: February 19, 2001
Received: February 23, 2001

Dear Dr. Maggiore:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical Laboratory Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): K003752

Device Name: BIOSAFE Capillary Blood Transport System for Testing Thyroid Stimulating Hormone (TSH)

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C. Indications for Use Statement

The BIOSAFE Capillary Blood Transport System for Testing Thyroid Stimulating Hormone (TSH) is intended for prescription distribution, and is a clinic-use device for collection and transportation of capillary blood for *in vitro* diagnostic quantitative determination of TSH. The device will be used for measuring whole blood TSH levels in human adults. This device is not intended for the diagnosis of thyroid disease in neonates.

Dean Cooper

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K003752

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-The-Counter Use ___
(Per 21 CFR 801.109)

(Optional Format 1-2-96)